



Mitchell E. Daniels, Jr.
Governor

Judith A. Monroe, M.D.
State Health Commissioner

Indiana State Department of Health

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MEMORANDUM

TO: Local Health Officers

FROM: Judy Monroe, MD
State Health Commissioner

DATE: July 31, 2009

RE: Authorization to Dispense Antivirals

Initially, the Indiana State Department of Health distributed antivirals and other material to local health departments from the (federal) Strategic National Stockpile for pre-positioning purposes only. On May 14, 2009, the Indiana State Department of Health authorized the dispensing of the Tamiflu® for oral suspension from the stockpile to uninsured/indigent individuals at the discretion of the local health officer.

As you know, the Tamiflu® for oral suspension product received by 71 local health departments was labeled to expire June 30, 2009. This product was enrolled in the Food & Drug Administration's (FDA) Shelf Life Extension Program (SLEP) prior to the distribution by the federal government to states. The FDA recently granted extended expiration dates from June 30, 2009, to May 31, 2011, for certain lot numbers of this product. (The affected lot numbers of the Tamiflu® for oral suspension product have not yet been posted to the CDC website.) In addition, the Centers for Disease Control & Prevention (CDC) received authorization from the FDA to support the dispensing of the product with the extended expiration date **without** the requirement to re-label. In lieu of re-labeling, the product must be accompanied by the appropriate FDA-approved fact sheet.

Please see the links below and attached documents for the updated information:

1. Letter of Authorization that includes authorization and conditions to dispense the Tamiflu® for oral suspension under the new shelf-life extended expiry date **without** the requirement for relabeling.
http://www.cdc.gov/h1n1flu/eua/pdf/fda_letter_tamiflu.pdf
2. Copy of Fact Sheet for Health Care Providers - <http://www.cdc.gov/h1n1flu/eua/tamiflu.htm>
3. Copy of Fact Sheet for Patients and Parents (provided **in lieu of relabeling** product with extended expiry dates) <http://www.cdc.gov/h1n1flu/eua/tamiflu.htm>

Recall that if states and local jurisdictions do not distribute or dispense the antivirals in accordance with state and local law and with the scope and conditions of the Emergency Use Authorization (EUA), liability protections afforded by the Public Readiness and Emergency Preparedness (PREP) Act may be affected.

In addition, a number of local health officers have continued to express concerns about the uninsured and indigent and their desire to be able to provide antivirals to individuals without the means to pay for a prescription. **The Indiana State Department of Health hereby authorizes the dispensing of Tamiflu® (capsules as well as the suspension) from the stockpile to uninsured/indigent individuals at the discretion of the local health officer.** Remember that the stockpiled antivirals in your possession represent 25% of the total quantity of antivirals reserved for your jurisdiction by the federal government. It is imperative that we are good stewards of these emergency supplies and resources. The dispensing of the stockpiled antivirals shall occur only in accordance with CDC's "Interim Guidance on Antiviral Recommendations for Patients with Novel Influenza A (H1N1) Virus Infection and Their Close Contacts", as updated by the CDC, located at: <http://www.cdc.gov/h1n1flu/recommendations.htm>. **Any entity (e.g. - hospital, pharmacy, physician's office) to whom the local health department distributes the antivirals to for dispensing must also comply with these requirements.** The local health department is accountable for the antivirals deployed to their jurisdiction.

Accompanying Documents:

- Emergency Use Authorization Letter – Tamiflu
- Fact Sheet for Health Care Providers – Tamiflu
- Fact Sheet for Patients – Tamiflu
- Memorandum from IPLA and Indiana Board of Pharmacy